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IP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/371,347	08/10/99	GRAVEL R	50004/003003

HM22/1115

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EXAMINER	
STEADMAN, D	
ART UNIT	**PAPER NUMBER**
1652	8

DATE MAILED: 11/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/371,347	GRAVEL ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 drawn to a nucleic acid encoding or complementary to a mammalian methionine synthase reductase polypeptide, classified in class 536, subclass 23.2.

II. Claims 9-12, drawn to a non-human animal encoding mutant mammalian methionine synthase reductase polypeptide, classified in class 800, subclass 8.

III. Claim 13, drawn to an antibody that binds methionine synthase reductase polypeptide, classified in class 530, subclass 387.1.

IV. Claim 14, drawn to a method of assaying for methionine synthase reductase polypeptide using an antibody that binds methionine synthase reductase polypeptide, classified in class 435, subclass 7.4.

V. Claim 15, drawn to a method for detecting sequence variants of mammalian methionine synthase reductase polypeptide, classified in class 435, subclass 6.

VI. Claims 16 and 18, drawn to a method of treating or preventing cancer, cardiovascular disease, or neural tube defects by inhibiting methionine synthase reductase, classified in class 514, subclass 789.

VII. Claims 17 and 18, drawn to a method of treating or preventing cardiovascular disease, or neural tube defects by administering a metabolite or cofactor classified in class 514, subclass 46.

VIII. Claim 19, drawn to a method of preventing cancer, cardiovascular disease, or neural tube defects by detecting increased risk of cancer, cardiovascular disease,

or neural tube defects followed by exposure to a metabolite or cofactor, classified in class 514, subclass 46.

IX. Claim 20, drawn to a method for screening modulators of methionine synthase reductase activity, classified in class 435, subclass 25.

X. Claim 21, drawn to a method for screening for modulators of methionine synthase reductase expression, classified in class 435, subclass 6.

XI. Claims 22-34, drawn to a method for detecting polymorphic MTRR, classified in class 435, subclass 4.

The inventions are distinct, each from the other because:

Groups I, II and III are patentably distinct from each other as the nucleic acid of Group I, the non-human animal of Group II and the antibody of Group III are unrelated as they do not share a similar structure, do not require each other for practice and have separate utilities, such as the nucleic acid of Group I used as a hybridization probe versus the non-human animal of Group II used as a model for disease versus the antibody of Group III used to affinity purify methionine synthase reductase.

The nucleic acid of Group I is unrelated to the methods of Groups IV, and VI-XI as it is neither made nor used by the methods of Groups IV, and VI-XI.

Groups I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the nucleic acid of Group I can be used for production of methionine synthase reductase.

The non-human animal of Group II is unrelated to the methods of Groups IV-XI as it is neither made nor used by the methods of Groups IV-XI.

Groups III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group IV can be used for affinity purification of methionine synthase reductase.

The antibody of Group III is unrelated to the methods of Groups V-XI as it is neither made nor used by the methods of Groups V-XI.

The methods of Groups IV-XI are independent as they comprise different steps, utilize different products and yield different results.

Claims 22-34 generic to a plurality of disclosed patentably distinct species comprising claims 23-27, drawn to a method of MTRR polymorphism detection by analyzing MTRR nucleic acid; claim 28, drawn to a method of MTRR polymorphism detection by analyzing MTRR polypeptide; claims 31 and 32, drawn to a method of MTRR polymorphism detection by analyzing MTHFR nucleic acid; claim 33, drawn to a method of MTRR polymorphism detection by analyzing MTHFR polypeptide; claim 34, drawn to a method of MTRR polymorphism detection by analyzing cobalamin levels. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and, although the inventions may or may not have the same classification numbers, have acquired a separate status in the art because of their recognized divergent subject matter and would result in an undue search burden on the Examiner, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The examiner can normally be reached Monday-Friday from 8:00 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Art Unit is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman

November 14, 2000

Rebecca Liddy

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